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PATENT  
Attorney Docket No.: 082368-008900US  
Client Reference No.: ONC-X0309P-US

TOWNSEND and TOWNSEND and CREW LLP

By: /Brien M. Bergner/  
Brien M. Bergner

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

NAKAMURA and FURUKAWA

Application No.: 10/589,594

Int'l. Filing Date: February 24, 2004

For: METHOD FOR DIAGNOSING  
COLORECTAL CANCERS

Confirmation No.: 8459

Examiner: Not Yet Assigned

Art Unit: 1645

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. In compliance with the requirements of 37 CFR §1.98(a)(2), copies of the references are enclosed. Also enclosed is a copy of the Search/Examination report corresponding to the PCT application.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement.

However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

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| Substitute for form 1449A/B/PTO   |   |    | <b>Complete if Known</b> |                        |                 |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Use as many sheets as necessary) |   |    | Application Number       | 10/589,594             |                 |
|   |   |    | Filing Date              | February 24, 2004      |                 |
|   |   |    | First Named Inventor     | Nakamura, Yusuke       |                 |
|   |   |    | Art Unit                 | 1645                   |                 |
|   |   |    | Examiner Name            | Not Yet Assigned       |                 |
| Sheet   | 1 | of | 1                        | Attorney Docket Number | 062368-008900US |

| U.S. PATENT DOCUMENTS |                       |   |                                |  |   |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials*    | Cite No. <sup>1</sup> | Document Number<br>Number Kind Code <sup>2</sup> (if present) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |

| FOREIGN PATENT DOCUMENTS |                       |                           |                     |                                   |                                |  |   |                          |
|--------------------------|-----------------------|---------------------------|---------------------|-----------------------------------|--------------------------------|--|---|--------------------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   |                     |                                   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>3</sup>           |
|                          |                       | Country Code <sup>2</sup> | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |                                |  |   |                          |
|                          | AA                    | WO                        | 00/50568            | A2                                | 06-31-2000                     | Incyte Pharmaceuticals, Inc.                       |   | <input type="checkbox"/> |
|                          | AB                    | WO                        | 01/50860            | A2                                | 06-23-2001                     | Millennium Predictive<br>Medicine, Inc.            |   | <input type="checkbox"/> |
|                          | AC                    | WO                        | 02/21996            | A2                                | 03-21-2002                     | ECG Biotechnology, Inc.                            |   | <input type="checkbox"/> |
|                          | AD                    | WO                        | 2004-001072         | A2                                | 12-31-2003                     | Oncotherapy Science, Inc.                          |   | <input type="checkbox"/> |
|                          | AE                    | EP                        | 0284362             | A2                                | 09-28-1998                     | Imperial Chemical Industries<br>PLC                |   | <input type="checkbox"/> |

| NON PATENT LITERATURE DOCUMENTS |                       |   |  |  |                          |
|---------------------------------|-----------------------|---|--|--|--------------------------|
| Examiner Initials *             | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |  |  | T <sup>2</sup>           |
|                                 | AF                    | BUCKHAULTS, Phillip, et al.; "Secreted and Cell Surface Genes Expressed in Benign and Malignant Colorectal Tumors," <u>Cancer Research</u> , October 1, 2001; pp. 6996-7001; 61:19.   |  |  | <input type="checkbox"/> |
|                                 | AG                    | KITAHARA, Osamu, et al.; "Alterations of Gene Expression during Colorectal Carcinogenesis Revealed by cDNA Microarrays after Laser-Capture Microdissection of Tumor Tissues and Normal Epithelia," <u>Cancer Research</u> , May 1, 2001; pp. 3544-3549; 61:9.   |  |  | <input type="checkbox"/> |
|                                 | AH                    | LIN, Yu-Min, et al.; "Molecular diagnosis of colorectal tumors by expression profiles of 50 genes expressed differentially in adenomas and carcinomas," <u>Oncogene</u> , June 13, 2002; pp. 4120-4128; 21:26.  |  |  | <input type="checkbox"/> |
|                                 | AI                    | YANAGAWA, Rempel, et al.; "Genome-Wide Screening of Genes Showing Altered Expression in Liver Metastases of Human Colorectal Cancers by cDNA Microarray," <u>Neoplasia</u> , September-October 2001; pp. 395-401; 3:5.  |  |  | <input type="checkbox"/> |
|                                 | AJ                    | ZHANG, Lin, et al.; "Gene Expression Profiles in Normal and Cancer Cells," <u>Science</u> , May 23, 1997; pp. 1268-1272; 273:5316.  |  |  | <input type="checkbox"/> |

|                    |                 |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached